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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,581

04/15/2004

John A. Salon

57453-AA-PCT-US/JPW/MJW

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01/12/2007

LUNDBECK RESEARCH USA, INC.

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/825,581

Applicant(s)

SALON ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 169-180 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 169-180 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/15/04 &amp; 6/16/04</u> .                                   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. Claims 169-180 are pending in the instant application. Claims 1-168 have been canceled as requested by Applicant in the preliminary amendment filed April 15, 2004.

All claims are currently under examination.

### ***Information Disclosure Statement***

2. PCT02/02744 listed in the information disclosure statement filed April 15, 2004 is missing from the list of references submitted by Applicant. Therefore it is requested that Applicants submit a copy of the references for consideration with their response to this Office Action.

### ***Priority***

3. This application filed under former 37 CFR 1.60 lacks the Patent Number of nonprovisional parent application 09/885,478. A statement reading "(now United States Patent No. 6,723,552)" should be included following the title in the first sentence of the specification.

### ***Specification***

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods of Identifying Melanin Concentrating Hormone Receptor Antagonists.

***Claim Objections***

5. Claims 179 and 180 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 179 is drawn to a mammalian cell which is nonneuronal, but is dependent upon claim 177, which is drawn to an insect cell. Claim 180 is drawn to a nonneuronal cell, but it dependent on claim 177, which is drawn to an insect cell.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 169-180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1 Claims 169-180 are indefinite because the independent claims recite “consisting essentially of a nucleic acid”, and the phrase “consisting essentially of” refers to compositions, so it is not clear how it pertains to a nucleic acid.

6.2 Claims 169-180 are also indefinite because claims 169, 170 and 174 recite “wherein the human MCH1 receptor is an isolated nucleic acid consisting essentially of a nucleic acid encoding a human MCH1 receptor containing consecutive amino acids, the sequence of which is identical to the sequence of the human MCH1 receptor encoded by the consecutive nucleotides

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having a sequence .....". First, the isolated nucleic acid is not the MCH1 receptor. Second, it is not clear how reciting "is identical to" differentiates the receptor from the encoded receptor; if the receptor is identical to another receptor, then it is the receptor.

6.3 Claims 169 and 176-180 are indefinite because claim 169 is an incomplete claim. Claim 169 encompasses looking for a decrease in MCH1 receptor activity when a chemical compound and a known MCH1 agonist are contacted with a cell expressing MCH1 receptor, however, there is no step of separately contacting cells with just the agonist so that a difference in activity can be determined. It is suggested that the claim be amended as follows:

"A process for determining whether a chemical compound is a human melanin concentrating hormone (MCH1) receptor antagonist which comprises contacting cells transfected with and expressing DNA encoding the human MCH1 receptor with the compound in the presence of a known human MCH1 receptor agonist, and contacting cells separately with only the agonist, under conditions permitting the activation of the human MCHI receptor, and detecting a decrease in human MCH1 receptor activity compared to cells contacted only with the agonist, so as to thereby determine whether the compound is a human MCHI receptor antagonist;"

#### ***Advisory Information***

7. Claims 175, 176 and 178 depend from claims 169, 170 and 172. Claims 169 and 170 are independent claims, however, claim 172 is not an independent claim, and the Examiner believes that Applicants intend claims 175, 176 and 178 to depend from claim 174 and not 172.

#### ***Conclusion***

8. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.


The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

  
EILEEN B. O'HARA  
PRIMARY EXAMINER